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appear on a line(s) immediately below the other words required by this section in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

- (1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and no less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or
- (2) Not less than one-half the height of the largest type used in the words "breaded shrimp sticks" or the other comparable words required by this section.

§ 102.57 Greenland turbot (Reinhardtius hippoglossoides).

"Greenland turbot" is the common or usual name of the food fish Reinhardtius hippoglossoides, a species of Pleuronectidae right-eye flounders. The term "halibut" may be associated only with Atlantic halibut (Hippoglossus hippoglossus) or Pacific halibut (Hippoglossus stenolepis).

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

Subpart A—General Provisions

Sec.

104.5 General principles.

Subpart B—Fortification Policy

104.20 Statement of purpose.

Subpart C—Specific Nutritional Quality Guidelines

104.47 Frozen "heat and serve" dinner.

AUTHORITY: 21 U.S.C. 321, 343, 371(a).

SOURCE: 42 FR 14327, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 104.5 General principles.

(a) A nutritional quality guideline prescribes the minimum level or range of nutrient composition (nutritional quality) appropriate for a given class of food.

- (b) Labeling for a product which complies with all of the requirements of the nutritional quality guideline established for its class of food may state "This product provides nutrients in amounts appropriate for this class of food as determined by the U.S. Government," except that the words "this product" are optional. This statement, if used, shall be printed on the principal display panel, and may also be printed on the information panel, in letters not larger than twice the size of the minimum type required for the declaration of net quantity of contents by §101.105 of this chapter. Labeling of noncomplying products may not include any such statement or otherwise represent, suggest, or imply the product as being, in whole or in part, in compliance with a guideline.
- (c) A product bearing the statement provided for in paragraph (b) of this section, in addition to meeting the requirements of the applicable nutritional quality guideline, shall comply with the following requirements:
- (1) The label of the product shall bear the common or usual name of the food in accordance with the provisions of the guideline and §§ 101.3 and 102.5(a) of this chapter.
- (2) The label of the product shall bear nutrition labeling in accordance with §§ 101.2 and 101.9 of this chapter and all other labeling required by applicable sections of part 101 of this chapter.
- (d) No claim or statement may be made on the label or in labeling representing, suggesting, or implying any nutritional or other differences between a product to which nutrient addition has or has not been made in order to meet the guideline, except that a nutrient addition shall be declared in the ingredient statement.
- (e) Compliance with a nutrient level specified in a nutritional quality guideline shall be determined by the procedures and requirements established in §101.9(g) of this chapter.
- (f) A product within a class of food for which a nutritional quality guideline has been established and to which has been added a discrete nutrient either for which no minimum nutrient

level or nutrient range or other allowance has been established as appropriate in the nutritional quality guideline, or at a level that exceeds any maximum established as appropriate in the guideline, shall be ineligible to bear the guideline statement provided for in paragraph (b) of this section, and such a product shall also be deemed to be misbranded under the act unless the label and all labeling bear the following prominent and conspicuous statement: "The addition of at the level (or "The addition of contained in) this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food," the blank to be filled in with the common or usual name of the nutrient(s) involved.

[42 FR 14327, Mar. 15, 1977, as amended at 63 FR 14818, Mar. 27, 1998]

Subpart B—Fortification Policy

§104.20 Statement of purpose.

(a) The fundamental objective of this subpart is to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to foods. The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over- or underfortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims for certain foods. The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles when adding nutrients to food. It is reasonable to anticipate that the Reference Daily Intakes (RDI's) as delineated in §101.9 of this chapter and

in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change the levels of specific RDI's as improved knowledge about human nutrient requirements and allowances develops. The policy set forth in this section is based on U.S. dietary practices and nutritional needs and may not be applicable in other countries.

- (b) A nutrient(s) listed in paragraph (d)(3) of this section may appropriately be added to a food to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease if:
- (1) Sufficient information is available to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients. Manufacturers contemplating using this principle are urged to contact the Food and Drug Administration before implementing a fortification plan based on this principle.
- (2) The food is not the subject of any other Federal regulation for a food or class of food that requires, permits, or prohibits nutrient additions. (Other Federal regulations include, but are not limited to, standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, nutritional quality guidelines established in subpart C of this part, and common or usual name regulations established in part 102 of this chapter.)
- (c) A nutrient(s) listed in paragraph (d)(3) of this section may appropriately be added to a food to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling, and processing, when:
- (1) The nutrient is shown by adequate scientific documentation to have been lost in storage, handling, or processing in a measurable amount equal to at least 2 percent of the Daily Reference Value (DRV) of protein and of potasium and 2 percent of the Reference Daily Intake (RDI) in a normal serving of the food.
- (2) Good manufacturing practices and normal storage and handling procedures cannot prevent the loss of such nutrient(s),